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United States District Court, N.D. Illinois, Eastern Division.

Toby BLOCK, individually and on behalf of all others similarly situated. Plaintiff,

ABBOTT LABORATORIES, Defendant.

No. 99 C 7457.

March 29, 2002.

MEMORANDUM, OPINION AND ORDER

ANDERSEN, J.

*1 Plaintiff, Toby Block, brings this putative class action on behalf of herself and those similarly situated against Defendant Abbott Laboratories, Inc. Plaintiff now moves for class certification pursuant to Federal Rule of Civil Procedure 23(b)(2). For the following reasons, Block's motion for class certification is denied.

BACKGROUND

Abbott Laboratories, Inc. ("Abbott") designs, manufactures and distributes a Total beta-hCG test kit. The kit is designed to be used with the Abbott AxSYM system, which is a computer system used by laboratories throughout the world to test human fluid specimens for a variety of conditions. The beta-hCG kit is used to test for the presence of human chorionic gonadotropin ("hCG"). An elevated hCG level indicates, among other things, pregnancy. When a woman has elevated hCG levels but is not experiencing an intra-uterine (or normal) pregnancy, elevated hCG levels can indicate extra-uterine (or ectopic) pregnancy.

In the absence of any pregnancy (normal or ectopic), elevated hCG levels indicate serious illnesses, including a deadly form of cancer known as choriocarcinoma. Indeed, the medical community and relevant textbooks recognize that elevated hCG levels are the most important market for the diagnosis and treatment of gestational trophoblastic disease and choriocarcinoma. This form of cancer can be so malignant that if hCG levels are consistently elevated without any sign of pregnancy, obstetrics and

gynecology textbooks recommend chemotherapy be initiated immediately. If hCG levels remain elevated even after chemotherapy, hysterectomy is the recommended course of treatment.

The purported class representative in this case is a 24-year old woman named Toby Block. Block was given a pregnancy test using the Abbott AxSYM test kit in 1997. The test indicated elevated hCG levels. However, Block was not pregnant. Due in large part to the fact that her hCG levels remained elevated, Block was subjected to a variety of medical tests to determine the cause of her high hCG levels. All of these tests were negative for any disease.

Two months after she initially was given the Abbott test, Block returned to her doctor for more tests. Again, an Abbott kit was used to test her hCG levels. The test results indicated continued elevated hCG levels. As a result of these readings, Block was diagnosed as having trophoblast disease and was immediately given chemotherapy. She received a four-day course beginning on December 31, 1997. A second four-day course began on January 8, 1998, and was discontinued after 3 days due to pulmonary difficulty. Nevertheless, Abbott test results still indicated elevated hCG levels, and a third course of chemotherapy was ordered.

However, shortly before she was to begin her third course of treatment, Block contacted Dr. Laurence Cole, Ph. D. at Yale University. Dr. Cole is a widely recognized expert in hCG testing, and he and his colleagues analyzed her blood using a different test kit. The results of these tests were negative for hCG. Dr. Cole concluded that Block had "phantom hCG immunoreactivity," which he attributed to the Abbott test, and that she did not have trophoblast disease.

*2 In 1999, Block filed the instant class action complaint alleging three causes of action. Specifically, she has alleged that Abbott is liable under: a) the common law theory of failure-to-warn; b) state consumer fraud and deceptive trade practices acts; and c) the tort of medical monitoring. She seeks certification of a class defined as:

All females residing in the United States who in the past were treated, are now being treated or in the future will be treated for trophoblast disease or for an ectopic pregnancy after receiving elevated hCG readings from Abbott's beta-hCG test pack used in conjunction with the Abbott AxSYM diagnostic testing systems.

As class relief under each of these theories, Block seeks: 1) injunctive relief ranging from letters to pathologists and physicians notifying them of the Case 1:00-cv-00458-SJD

risks associated with "false positive" test results to an apology from Abbott's chief executive officer to the class for issuing a press release which Block has characterized as a "vituperative broadside" (*see* Block Supp. Brief at 2); and 2) a medical monitoring fund to pay for "medical testing to provide early detection of latent disease" associated with chemotherapy. (Complaint at ¶¶ 66, 92, 106.)

DISCUSSION

A party seeking to represent a class of similarly situated individuals has the burden of establishing that class certification is proper under Federal Rule of Civil Procedure 23. Retired Chicago Police Assoc. v. City of Chicago, 7 F.3d 584, 596 (7th Cir.1993). The Court must determine the propriety of class certification with reference to the requirements of Rule 23 and not to whether the plaintiff will ultimately prevail on the merits of his claim. "[N]othing in either the language or history of Rule 23 ... gives a court any authority to conduct a preliminary inquiry into the merits of a suit in order to determine whether it may be maintained as a class action." Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177, 94 S.Ct. 2140 (1974).

In determining whether class certification is proper under Rule 23, the Court must undertake a two-step analysis. The Court must first determine whether the initial requisites for class certification delineated in Rule 23(a) are satisfied: (1) that the class is so numerous that joinder of all members is impracticable (numerosity); (2) that there are questions of law or fact common to the class (commonality); (3) that the claims or defenses of the representative parties are typical of the claims or defenses of the class (typicality); and (4) that the representative parties will fairly and adequately protect the interests of the class (adequacy of representation). Second, the Court must determine whether the proposed class satisfies one of the subparts of Rule 23(b). In this case, Block seeks certification under Rule 23(b)(2), which requires that "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed.R.Civ.P. 23(b)(2). With these principles in mind, we turn to whether Block has satisfied the requirements for class certification under Rule 23.

I. Numerosity

*3 Rule 23(a)(1) requires that the class be "so

numerous that joinder of all class members is impracticable." Fed.R.Civ.P. 23(a)(1). Because there is no mystical number at which the numerosity requirement is established, courts have found this element satisfied when the putative class consists of as few as 10 to 40 members. See Markham v. White, 171 F.R.D. 217, 221 (N.D.Ill.1997) (35-40 class members); Hendricks-Robinson v. Excel Corp., 164 F.R.D. 667, 671 (C.D.Ill.1996) (38 class members); Riordan v. Smith Barney, 113 F.R.D. 60, 62 (N.D.Ill.1983) (29 class members). Although the plaintiff need not allege the exact number or identity of the class members, the plaintiff ordinarily "must show some evidence or reasonable estimate of the number of class members." Long v. Thornton Township High Sch. Dist., 82 F. R.D. 186, 189 (N.D.Ill.1979). The Court is permitted to "make common sense assumptions in order to find support for numerosity." Cannon v. Nationwide Acceptance Corp., 1997 WL 139472, at *2 (N.D.Ill. March 25, 1997) (quoting Evans v. United States Pipe & Foundry, 696 F.2d 925, 930 (11th Cir.1983)).

Block does not allege the total number of individuals included in the proposed class. Nonetheless, the declaration of Dr. Cole, along with the number of test kits sold by Abbott on an annual basis, provides a reasonable basis for satisfying the numerosity requirement. Over the course of his study of the phenomenon surrounding these test kits, Dr. Cole himself has diagnosed almost twenty patients with "phantom hCG immunoreactivity." Given the volume of test kits sold and distributed throughout the country, it is safe to assume there are hundreds of women who similarly have experienced this problem. Therefore, we believe that the numerosity requirement of Rule 23(a)(1) has been satisfied.

II. Commonality and Typicality

Commonality exists if the class members share common questions of law or fact. The requirement is usually satisfied when a common nucleus of operative facts unites a class. *Rosario v. Livaditis*, 963 F.2d 1013, 1018 (7th Cir.1992). The presence of some factual variations among the class members does not defeat commonality, so long as there is at least one question of law or fact common to the class. *Id.* at 1017. The typicality requirement of Rule 23(a)(3) is closely related to the commonality requirement of Rule 23(a)(2). *Ruiz v. Stewart Assoc.*, *Inc.*, 171 F.R.D. 238, 242 (N.D.III.1997). A named plaintiff's claim is typical if it arises from the same event or practice or course of action that gives rise to the claims of other class members and if his or her claims are based on the same legal theory. *Rosario*,

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963 F.2d at 1018. However, "[i]f proof of [plaintiff's] claims would not necessarily prove all of the proposed class members' claims," she fails the typicality prong of Rule 23(a). Williams v. Ford Motor Co., 192 F.R.D. 580, 586 (N.D.III.2000) (citing Ruiz v. Stewart Assoc., Inc., 167 F.R.D. 402, 405 (N.D.Ill.1996)). We will address each of Block's three causes of action in the context of these class action requirements.

A. Failure-to-Warn Count

*4 In her complaint, Block asserts that the question of whether Abbott provided adequate warnings about false positives generated by their test kits is common to the entire class and that Block's claims concerning these warnings are typical of those of the dass she seeks to represent. We disagree. There are a number of issues surrounding this case which lead us to conclude that the requirements of commonality and typicality are not as easily satisfied as Block would have us believe.

For example, we are very troubled by the prospect of having to resolve the highly individualized issue of proximate cause with respect to the failure-to- warn claim. In response to our concerns regarding proximate cause, Block argues that, since the class is not seeking damages but rather is seeking injunctive relief, individual issues of proximate causation are not relevant. (See Reply Br. at 11.) This argument cannot be correct. In order to be entitled to the relief she seeks on behalf of the class with respect to the failure-to-warn count, be it injunctive or legal, it is beyond cavil that Block must establish the core elements of the underlying failure-to-warn claim. While failure-to- warn law may vary from state to state, all states which recognize such a claim require, at a minimum, proof of causation and damages. See 63A Am.Jur.2d Products Liability § 1108.

Therefore, before even reaching the issue of whether Block and the class she purports to represent are entitled to the injunctive relief she seeks, she must first establish that the issues of proximate causation are common to the class. Block's argument that somehow the requirement to establish causation is eliminated because she seeks only injunctive relief on behalf of the class must be rejected. See Mace v. Van Ru Credit Corp, 109 F.3d 338, 346 (7th Cir.1997) (The Rules Enabling Act, 28 U.S.C. § 2072, mandates that the application of Rule 23 cannot "abridge, enlarge or modify any substantive right"); Cimino v. Raymark Indus., Inc., 151 F.3d 297, 312 (5th Cir.1998) (Rule 23 "does not alter the required elements which must be found to impose liability and

fix damages.").

Having decided that proximate causation is a class wide consideration even when injunctive relief is sought on behalf of the class, we find the prospect of class certification in this case particularly daunting. The determination of causation for each class member necessarily would depend on a variety of individualized considerations. A few of these considerations include: 1) whether the class member's physician and the laboratories that performed the tests read or were aware of the warnings in the package inserts accompanying the Abbott tests; 2) whether the physicians or laboratories were independently aware of the risks or limitations of the tests from medical literature or other sources: 3) the substance of communications between laboratories that performed the tests and the physicians who received the test results; 4) whether and to what extent the physicians relied on the Abbott tests in making diagnosis and treatment decisions; and 5) whether the physician also relied on the class member's clinical symptoms or other information in making diagnosis and treatment decisions. Several courts confronted with a similar panoply of individual issues have concluded that commonality and typicality requirements were not satisfied. See, e.g., In re American Med. Sys., Inc., 75 F.3d 1069, 1081 (6th Cir.1996) (each class member's physician would "be required to testify to determine what oral and written statements were made to the physician, and what he in turn told the patient, as well as issues of reliance, causation and damages"); Bethards v. Bard Access Sys., Inc., 1995 WL 75356, at *4 (N.D.Ill. Feb. 22, 1995) (each potential class member was treated differently according to their individual medical needs).

*5 In addition, we are troubled by the prospect of having to apply the laws of 51 jurisdictions to resolve the failure-to-warn claims of the proposed class. In Block's initial memorandum in support of her motion for class certification, she asserts that there are six different standards used in various jurisdictions to assess product liability claims. These include the risk/utility test (followed in 17 jurisdictions), the consumer expectation test (followed in jurisdictions), a combination of the risk/utility and consumer expectation tests (followed in 11 jurisdictions), the reasonably prudent manufacturer test (followed in 3 jurisdictions), the fit for ordinary use test (followed in 4 jurisdictions), and the unreasonably dangerous test (followed in 2 jurisdictions). (See Block Initial Brief at 16.) However, as Abbott correctly points out, there are also numerous affirmative defenses which different

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jurisdictions allow to combat failure-towarn claims, such as comparative or contributory negligence or fault and product misuse. *Gee* Abbott Opposition Brief at 7, citing 63A Am.Jur.2d *Products Liability* § 1109.) Notwithstanding Block's argument that the presence of affirmative defenses is immaterial because the class is seeking only injunctive relief, we conclude that the variations in state law for failure-towarn claims and the presence of multiple state-specific affirmative defenses necessitate a finding that the class issues presented with respect to this count fail to satisfy the commonality and typicality requirements.

B. Consumer Fraud Count

The second cause of action raised by Block in her motion for class certification is based on state consumer fraud statutes. As with the failure- to-warn claim, Block must establish that there are common questions of law and fact and that her personal claims are typical of the class she seeks to represent with respect to these consumer fraud acts. We conclude that she has once again not satisfied this burden.

As we indicated in our rulings on the motions to dismiss in the individual actions against Abbott currently pending before this Court, we have ongoing concerns as to whether the individual plaintiffs will ultimately be able to satisfy their burden at trial on the issue of Abbott's liability under certain state consumer fraud/protection statutes. Specifically, we have indicated that we were interested in learning whether the individual plaintiffs were actually "consumers" of these test kits as well as discovering the extent of any reliance the plaintiffs placed on alleged misrepresentations made by Abbott regarding the nature or accuracy of its kits. See Glazer v. Abbott Lab., Inc., 2001 WL 1568882, at *3 (N.D.III.Dec. 6, 2001); Hofmann v. Abbott Lab., Inc., 2001 WL 1558299, at *4 (N.D.III.Dec. 5, 2001).

Any misgivings we may have with respect to the individual plaintiffs and their consumer fraud allegations are multiplied when considered in connection with the certification of a nation-wide class. Across the country, states have enacted consumer protection statutes which vary on a wide range of important issues, including subtleties in standards of proof, procedure, and remedies. As very clearly illustrated in Abbott's brief in opposition to class certification, some interesting differences between the various state statutes are: 1) what conduct is actionable (New Jersey proscribes "any unconscionable commercial practice" whereas California proscribes 23 specific activities); 2)

whether individual reliance is required (Michigan requires proof of actual, individual reliance); 3) what level of scienter is required (Kansas requires proof of intent to deceive); 4) whether a class action is allowed (South Carolina specifically prohibits class action claims); 5) whether a written demand to the defendant is required (Georgia requires a written demand to the defendant 30 days before filing suit; see also, Gibbs v. Abbott Lab., Inc., 2001 WL 1558279, at *3-4 (N.D.Ill.Dec. 5, 2001)); 6) whether involvement by the state Attorney General is required (Louisiana requires that a copy of the complaint be mailed to the attorney general when the suit is filed, and Mississippi requires plaintiffs to try to settle claims through an attorney general-approved settlement process); and 7) what limitations period applied (Arizona provides for a one-year limitations period whereas Maine provides a six-year limitations period). See Abbott Opposition Brief at 8, citing John S. Kiernan, et al., <u>Developments in Consumer</u> Fraud Class Action Law, 537 PLI/Pat 237, 277-84 (1998)

*6 In addition, another problem that arises when considering a nation-wide class action involving state consumer protection statutes is the availability of injunctive relief. In Indiana and Louisiana, for example, injunctive relief can only be sought by the state Attorney General. See Ind.Code Ann. § 24-5-0,5-4 (2000); <u>La. R.S. 51:1407</u>, <u>51:1409</u> (2000). When confronted with this problem, Block was forced to acknowledge that the proposed class would have to exclude women from states that prohibit private claimants from seeking injunctive relief under that state's consumer fraud act. See Block Reply Brief at 14 n. 5). As an alternative, Block requests that we certify a subclass of residents of the other 49 jurisdictions for purposes of this claim. We must decline this invitation. It is clear that there are so many different legal considerations involving state consumer fraud statutes that certification of the proposed nation-wide class is impractical. Would we be required to certify a subclass of all jurisdictions except South Carolina because it prohibits class actions for consumer protection claims? Would we need subclasses for plaintiffs from states that require proof of individual reliance and those that do not? Would it also be necessary to certify subclasses based on the different statutes of limitations? These issues alone convince us that certification of a class action with respect to the consumer fraud claim would be a logistical and procedural nightmare. Therefore, we find that Block has not demonstrated the commonality or typicality necessary to satisfy Rule 23(a) for the consumer fraud count.

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C. Medical Monitoring Count

Originally in her complaint, Block requested that a medical monitoring program be established on behalf of all class members. Specifically, this program would be funded by the defendant and it would serve to: 1) notify the class of the defects and the potential medical harm associated with false positive results; 2) provide funds for medical testing to provide early detection of latent disease associated with chemotherapy and hysterectomy; and 3) gather and forward to treating physicians information relating to the diagnosis and treatment of injuries which may result from any unnecessary medical treatment resulting from false positive readings. (Complaint at ¶ 117.) However, in her reply brief in support of her class certification motion, Block recognized that "certifying the class with respect to a separate cause of action for medical monitoring is problematic." (Block Reply Brief at 15.) Accordingly, she withdrew her request that a class be certified with respect to the separate medical monitoring claim. Therefore, we deny the motion for class certification as to this claim.

III. Adequacy of Representation

The adequacy of representation prong requires that the class representative have a sufficient stake in the outcome to ensure zealous advocacy, that the class representative does not have antagonistic or conflicting claims with other class members, and that counsel for the named plaintiff is experienced, qualified, and generally able to conduct the litigation. See Retired Chicago Police Ass'n, 7 F.3d at 598; Gammon v. GC Services Ltd. Partnership, 162 F.R.D. 313, 317 (N.D.Ill.1995) (citations omitted). Further, it is well-settled in this circuit that a named plaintiff seeking to represent a class of similarly situated individuals must individually have standing to seek the relief requested on behalf of the class. See Mintz v. Mathers Fund, Inc., 463 F.2d 495, 499 (7th Cir.1972) ("A plaintiff who is unable to secure standing for [herself] is certainly not in a position to insure the adequate representation of those alleged to be similarly situated"); Ladegaard v. Hard Rock Concrete Cutters, Inc., 2000 WL 1774091, at *6 (N.D.III.Dec. 1, 2000) (same).

*7 The Supreme Court has characterized the doctrine of standing as "an essential and unchanging part of the case-or-controversy requirement of Article III" of the Constitution. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130 (1992). "In essence the question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or

particular issues." Warth v. Seldin, 422 U.S. 490, 498, 95 S.Ct. 2197 (1975). A party seeking to invoke a federal court's jurisdiction must demonstrate three things: (1) an "injury in fact"--an invasion of a legally recognized interest which is concrete actual or imminent, and particularized, conjectural or hypothetical; (2) a causal link between that injury and the defendant's action, such that the injury is fairly traceable to the action complained of; and (3) that a favorable decision will likely redress the injury. See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 180-81, 120 S.Ct. 693 (2000) (citing *Lujan*, 504 U.S. at 560-61); Sierakowski v. Ryan, 223 F.3d 440, 442-43 (7th Cir.2000); Perry v. Village of Arlington Heights, 186 F.3d 826, 829 (7th Cir.1999).

In this case, we find that Block does not have standing to pursue this action on behalf of the class-and thus does not satisfy the adequacy prong of Rule 23(a)--because she cannot satisfy the third prong of the Article III standing test (i.e. the "redressability" requirement). We must reach this conclusion because we are unable to discern how the injuries alleged in this case by Block can be redressed by means of an injunction requiring Abbott to send notice about the potential for false positives to physicians and pathologists who are not before the Court as parties. It is a fundamental principle of the Article III standing requirement that any relief fashioned by the Court must actually be able to redress the alleged injury. This is not possible when the primary targets of the proposed relief are not subject to the jurisdiction of the Court in that particular case. See Lujan, 504 U.S. at 569 ("[R]esolution by the District Court would not have remedied respondents' alleged injury anyway, because it would not have been binding upon the agencies. They were not parties to the suit, and there is no reason they should be obliged to honor an incidental legal determination the suit produced"); ASARCO, Inc. v. Kadish, 490 U.S. 605, 615, 109 S.Ct. 2037 (1989) ("Whether the association's claims of economic injury would be redressed by a favorable decision in this case depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict.").

In this case, Block seeks an injunction which would require Abbott to send notice of the alleged hazards which can result from the use of the hCG test kits to physicians and pathologists throughout the country. The problem is that these physicians and pathologists are third parties who are not subject to the jurisdiction of this Court. The consequence of this

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situation is that, even if we were to grant the relief Block requests on behalf of the class and require Abbott to send out the desired warnings, we have no confidence that the physicians would actually read the notice or change their practices as a result. We have no desire to expend valuable judicial resources to certify a class and then later discover that the whole process was futile because the pathologists and physicians were not required to read and comply with the judicially mandated warnings. If Block believes that Abbott should provide additional warnings, then the appropriate state and federal regulatory agencies can more effectively ensure that the proper warnings reach their intended audience. Therefore, we conclude that Block does not have standing to pursue this action because she does not satisfy the redressability prong of the Article III standing test. Consequently, she is not an adequate representative of the class pursuant to Rule 23(a)(4).

IV. Requirements of Rule 23(b)(2)

*8 Rule 23(b)(2) permits certification of a class if "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Rule 23(b)(2) is generally "invoked in cases where injunctive or declaratory relief is the primary or exclusive relief sought." Buycks-Roberson v. Citibank Fed. Sav. Bank, 162 F.R.D. 322, 335 (N.D.III.1995). A court considering Rule 23(b)(2) certification must find that the injunctive or declaratory relief is "primary" or "exclusive" because Rule 23(b)(2) certification creates "binding litigation on all class members without guarantees of personal notice and the opportunity to opt out of the suit." Lemon v. International Union of Operating Engineers, Local No. 130, 216 F.3d 577, 580 (7th Cir.2000). In Lemon, the Seventh Circuit also held that, before a Rule 23(b)(2) class can be certified, the interests of the class members must be "cohesive and homogenous such that the case will not depend on adjudication of facts particular to any subset of the class nor require a remedy that differentiates materially among class members." Id. at 580.

As we have discussed in some detail above, the interests of the class members in this case are neither cohesive nor homogeneous. Aside from the medical monitoring claim which Block has abandoned, the failure-to-warn and consumer fraud claims are so saturated with factual and legal differences between and among the potential class members that certification in this case would be imprudent. Block has failed to persuade this Court that it can

reasonably deal with widely varying laws of 51 separate jurisdictions with respect to the failure-to-warn and consumer fraud counts. Significant variations in applicable state laws, combined with overwhelming factual variations in each class member's case, preclude any finding that "the interests of the class members are cohesive and homogeneous." *Lemon*, 216 F.3d at 580. Therefore, we find that Block has failed to establish that the proposed class satisfies the requirements of Rule 23(b)(2).

CONCLUSION

After a careful review of the parties' submission in this case as well as numerous conversations with counsel for both sides, we find that certification of a nation-wide class is not appropriate in this case. While the class action mechanism is often the best means to resolve the disputes of plaintiffs who are geographically diffuse, this is not one of those cases. In fact, it is our opinion that individual prosecution of the products liability suits against the defendant in this case is the preferable avenue to recover damages associated with false positive results. In this Court, all of the individual plaintiffs have, at least partially, survived motions to dismiss. Additionally, in a widely reported case from a Washington state court, a plaintiff and her husband successfully sued Abbott and the University of Washington Medical Center for damages stemming from unnecessary chemotherapy and a hysterectomy she endured as a result of false positive results. See Rufer v. Abbott Lab., Inc., et al., No. 99-2-27909-8 (Wash.Sup.Ct.2001). The upshot of the verdict has been a dramatic warning to physicians, pathologists and patients. Moreover, the size of the verdict (\$15 million) provides Abbott with an incentive to improve its own communications to health care professionals without the need for the type of class oversight and relief sought here. (Indeed, Abbott has already issued special warnings both before and after this verdict). Therefore, for the foregoing reasons, we deny the plaintiff's motion for class certification pursuant to Federal Rule of Civil Procedure 23(b)(2).

*9 It is so ordered.

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